

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A	

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF MELVIN ANHALT, M.D.**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court limit the opinion testimony of Defendants' witness, Melvin Anhalt, M.D. ("Dr. Anhalt"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Anhalt is a Board certified Urologist who maintains a practice in Houston, Texas and Plaintiffs do not challenge his qualifications as such. Exhibit B, Dr. Anhalt TVT and TVT-O Report, pp. 1-2 and curriculum vitae ("CV"), Exhibit C, Dr. Anhalt CV. However, Dr. Anhalt offers opinions related to the material properties of polypropylene mesh (Exhibit B, pp. 15-16), the adequacy of studies and/or clinical trials (Exhibit B, pp. 17-20), the regulatory framework for Defendant's polypropylene mesh (Exhibit B, p.20), and the design of the polypropylene mesh products (Exhibit B, pp. 20-22). Indeed, at his deposition, Dr. Anhalt acknowledged that he has limited, if any, experience in many of these areas and affirmatively disavowed any expertise

beyond his care and treatment of individual patients. Plaintiffs address each of the areas in which Dr. Anhalt lacks sufficient credentials and expertise below.¹

In sum, Dr. Anhalt's opinions are both contrary to law and present a serious risk of confusing the issues and misleading the jury in this case. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.')(citing *Daubert*, 509 U.S. at 596). As this Court noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, at *42-43 (S.D.W.V. 2013). Here, Dr. Anhalt is not qualified in many of the areas in which he opines and his opinions and testimony run afoul of this Court's prior rulings. Thus, Dr. Anhalt should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. See also *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). However, the witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be

¹ At his deposition, Dr. Anhalt testified that approximately 50% of his current practice involves the care and treatment of women. Of this, only 15-16% involves the treatment of stress urinary incontinence (SUI). See April 2, 2016 deposition of Dr. Anhalt (Dr. Anhalt Dep.), 73:21-74:12 (attached as Exhibit D).

qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. See also, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). As this Court has noted, qualifications in one area of practice does not necessarily mean “that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods of facts to this case.’” *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013). Indeed, many of Dr. Anhalt’s opinions lack the requisite methodology (as he offers none) and, additionally, he fails to possess the qualifications to issue such opinions.

ARGUMENT

I. THE COURT SHOULD EXCLUDE DR. ANHALT’S OPINIONS RELATED TO THE SCIENTIFIC, CHEMICAL OR STRUCTURAL MAKE-UP OF ETHICON’S TVT AND TVT-O DEVICES; DESIGN OF THE TVT AND TVT-O DEVICES; PROPERTIES OF POLYPROPYLENE; POROSITY AND MESH WEIGHT; AND MECHANICAL CHANGES OF POLYPROPYLENE MESH, INCLUDING DEGRADATION AND FLAKING AS UNRELIABLE AND OUTSIDE HIS AREA OF EXPERTISE.

Even though Dr. Anhalt does not have any experience in material science and has never analyzed, tested, designed, researched or studied polypropylene mesh, he arbitrarily offers opinions in his report regarding these issues. Exhibit B, pp. 15-16, 19-21. Dr. Anhalt’s opinions on these issues must be excluded in their entirety because his opinions are unreliable, would confuse the trier of fact and, importantly, Dr. Anhalt is not qualified to render opinions on these topics. Indeed, Dr. Anhalt has not authored any peer-reviewed literature on any of these topics, has not participated in clinical trials related to the mesh, does not possess any specialized

education or training on these issues and has affirmatively disavowed any expertise. See Exhibit D, 54:11-54:23; 59:3-59:16; 68:3-68:24; 69:9-69:11; 70:2-72:9; 133:7-133:9; 134:5-134:8; 142:2-142:11; 147:1-147:21; 148:4-148:18; 149:3-153:15. Dr. Anhalt does not even view himself as an expert on these topics and, under sworn testimony, he conceded as such:

Q. Do you consider yourself an expert with respect to design controls regarding the manner in which medical devices are manufactured?

A. No.²

Q. Doctor, are you offering any opinions on whether any aspect of the design of the product causes fraying of the mesh?

A. No.

Q. And are you rendering any opinions on whether any aspect of the design of the product causes curling of the mesh?

A. No.

Q. Okay. And are you offering any opinions on whether any aspect of the design of the product causes bunching of the mesh?

A. No.

Q. Okay. And are you rendering any opinions with respect to any aspect of the design of the product that may be causing roping of the mesh?

A. No.³

Q. Do you consider yourself an expert on polymers?

A. No.⁴

Q. Do you consider yourself an expert with respect to biomaterials?

A. No.⁵

Q. . . . And you do not consider yourself an expert on pathology?

A. Correct.⁶

Q. . . . And you are not a toxicologist. Is that correct?

A. Yes, I am not.⁷

Q. . . . And do you have any expertise in epidemiology?

² Exhibit D, 70:19-22.

³ Exhibit D, 149:3-18.

⁴ Exhibit D, 71:2-4.

⁵ Exhibit D, 71:8-10.

⁶ Exhibit D, 71:22-24

⁷ Exhibit D, 72:1-3.

A. No.⁸

Q. Do you consider yourself an expert with respect to the material polypropylene?

A. No.⁹

Q. . . . And you're not rendering any opinions with respect to what about the material may cause roping, are you?

A. No.¹⁰

Q. . . . And you're not rendering any opinions with respect to what with the material may cause fraying, are you?

A. No.¹¹

Q. Are you offering any opinions with respect to the reactivity of polypropylene mesh?

A. No.¹²

Q. Are you offering any opinions with respect to degradation of polypropylene mesh?

A. I haven't seen it, but, no, I'm not offering an opinion.¹³

Q. . . . And you're not rendering any opinions with respect to what in the material may cause flaking?

A. I am not rendering any opinions on that.¹⁴

Q. And you don't have any opinions with respect to the material aspect of the -- with respect to pore size from a materials aspect?

A. Correct.¹⁵

Q. . . . And you don't have any opinions that you're rendering here today with respect to the elements of the design that factor into the pore size of the mesh?

A. I do not.¹⁶

⁸ Exhibit D, 72:4-6.

⁹ Exhibit D, 150: 12-14.

¹⁰ Exhibit D, 148:11-14.

¹¹ Exhibit D, 148:15-18.

¹² Exhibit D, 150: 15-17.

¹³ Exhibit D, 150: 18-21.

¹⁴ Exhibit D, 148:7-10.

¹⁵ Exhibit D, 152:16-19.

¹⁶ Exhibit D, 152:20-24.

An expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation. *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997). Here, Dr. Anhalt does not extend himself to be a qualified expert in this area but yet he makes statements based on his "personal experience" in limited circumstances. For example:

Q. . . . [Y]ou had mentioned ... that you're not a scientist and you're not a materials persons, your focus is on treating patients. Correct?

A. Correct.¹⁷

Q. . . . Have you ever done any bench research with respect to polypropylene mesh?

A. No.

Q. Have you ever done any lab research with respect to polypropylene mesh?

A. No.¹⁸

These opinions exceed the bounds of Dr. Anhalt's qualifications and, by his own admission, his experience and education. Similarly, Dr. Anhalt does not utilize any methodology, nonetheless reliable methodology regarding the mechanical and material properties of polypropylene mesh. At his deposition, Dr. Anhalt testified that he has never conducted any pathological analysis or sought out additional information regarding mesh pathology. See Exhibit D, 71: 14-24, 72:7-17, 146:18-147:3. Indeed, one of the flaws in Dr. Anhalt's opinions is that they are solely premised on his assumption that it may happen in only limited circumstances (or that he has read about it in literature) – but that it has not happened to him. See Exhibit D, 127:22-128:4, 132:18-133:9, 134:5-23, 142:24-143:12, 147:16-148:10,

¹⁷ Exhibit D, 59:3-7.

¹⁸ Exhibit D, 59:11-16.

150:18-21. However, as stated above, even Dr. Anhalt concedes that he is not an expert on these issues.

Plaintiffs' respectfully request that the Court preclude Dr. Anhalt from rendering opinions or testimony regarding mesh design, as well as the chemical or biomaterial properties of polypropylene mesh, including but not limited to porosity, mesh weight, mesh flexibility/stiffness, flaking, roping, curling, fraying, degradation, and mesh cut (i.e., mechanical vs. laser cut mesh).

II. THE COURT SHOULD EXCLUDE DR. ANHALT'S OPINIONS REGARDING THE ADEQUACY OF CLINICAL TRIALS AS UNRELIABLE AND OUTSIDE DR. ANHALT'S AREA OF EXPERTISE

Similarly, Plaintiffs' respectfully request that the Court preclude Dr. Anhalt from rendering opinions or testimony regarding the adequacy of any clinical trials. Dr. Anhalt offers his opinion regarding the adequacy of studies and/or clinical trials regarding TVT products in his general report. Exhibit B, pp. 17-20. However, Dr. Anhalt's CV and own testimony reveal the complete lack of any background or expertise in the area of clinical trials/studies. In support of his opinion, Dr. Anhalt provides a list of published articles. However, Dr. Anhalt admits that he has not thoroughly reviewed many of the articles listed in his reliance list and has read only summaries of the articles. See Exhibit D, 40:2-15. Further, Dr. Anhalt has never participated in any clinical trials with respect to pelvic mesh products. See Exhibit D, 68:11-24.

Q. Okay. Have you been involved in any clinical trials with respect to pelvic mesh products?

A. No.¹⁹

Nor has Dr. Anhalt ever participated in the peer review of any literature related to pelvic mesh clinical trials or related studies. See Exhibit D, 68:3-10. Dr. Anhalt has treated numerous

¹⁹ Exhibit D, 68:11-13.

patients over the years and has an opinion regarding his personal use of Defendant's product. However, this does not qualify Dr. Anhalt as an expert on clinical studies related to the TVT products – or any other type of clinical study. Indeed, Dr. Anhalt's opinion regarding the adequacy of clinical trials lacks any basis and Dr. Anhalt has failed to demonstrate that he has the requisite training, education, experience or knowledge required under *Daubert* to provide reliable expert testimony to the jury regarding clinical trials and studies. Plaintiffs respectfully request that the Court preclude Dr. Anhalt from rendering opinions or testimony regarding the adequacy of clinical trials or other studies regarding TVT products.

III. THE COURT SHOULD EXCLUDE DR. ANHALT'S OPINIONS REGARDING REGULATORY ISSUES AS UNRELIABLE AND OUTSIDE DR. ANHALT'S AREA OF EXPERTISE

In his report, Dr. Anhalt offers an opinion regarding the regulatory framework for Defendant's polypropylene mesh. Exhibit B, p. 20. Again, Dr. Anhalt's background, education, training and experience do not provide the necessary qualifications to support an expert opinion relating to regulatory issues. In Dr. Anhalt's own testimony, he states he: 1) has never been an FDA consultant (Exhibit D, 60:17-18); 2) has never been employed by the FDA (Exhibit D, 60:19-21); and 3) has never participated on an FDA advisory board on any topic (Exhibit D, 60:22-24). Dr. Anhalt admits that he has never sent any communications to the FDA nor reported any mesh related adverse events to the appropriate FDA department. See Exhibit D, 61:11-17. In fact, at his deposition Dr. Anhalt states:

Q: Do you hold yourself out to be an expert on FDA regulatory matters?

A. No.

Q. Do you have any specific expertise with respect to classification of medical devices at the FDA?

A. No.

Q. Do you have any expertise with respect to the way in which the FDA reviews products, mesh products, prior to placing them on the market?

A. No.²⁰

Based on Dr. Anhalt's own acknowledgement and concession regarding his lack of regulatory expertise, Plaintiffs' respectfully request that the Court preclude Dr. Anhalt from rendering opinions or testimony regarding any regulatory issues as they pertain to the TVT products. Even if Dr. Anhalt did possess the requisite qualifications, as briefed many times to this Court, such opinions are based on inadmissible evidence and therefore must be excluded. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 578 (S.D. W. Va. 2014). Indeed, this Court has repeatedly held that evidence related to the FDA regulatory requirements and its 510(k) process are inadmissible and misleading. See, e.g., *Lewis v. Johnson & Johnson*, 991 F. Supp. 748, 756 (S.D.W.V. 2014).

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Anhalt is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Dr. Anhalt's opinions, Ethicon cannot carry this burden and Dr. Anhalt's testimony should be excluded and/or limited as set forth herein.

Dated: April 21, 2016

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²⁰ Exhibit D, 70:5-15.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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